REDACTED DOCUMENTS RELATING TO DOCKET 7292

EXHIBIT A – Previously filed redacted in DKT 8118

EXHIBIT B – Filed redacted

IN THE CIRCUIT COURT OF THE SEVENTEENTH JUDICIAL CIRCUIT IN AND FOR BROWARD COUNTY, FLORIDA

CLARE AUSTIN,

Plaintiff,

-VS- CASE NO. 15-008373
Div: 07

C.R. BARD, INC., a foreign corporation and BARD PERIPHERAL VASCULAR, INC., an Arizona corporation, MATTHEW ROBBINS, MD., and CLEVELAND CLINIC FLORIDA,

Defendants.

VIDEOTAPED DEPOSITION OF.
MARK J. EISENBERG, M.D., M.P.H.
ON WEDNESDAY, AUGUST 17, 2016
IN MONTREAL, QUEBEC, CANADA.

VIDEOGRAPHER: DAVID OXILIA
COURT REPORTER: C.L. KLEIN

APPEARANCES:
FOR BARD DEFENDANTS:
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WITNESS: MARK J. EISENBERG, M.D., M.P.H.

INDEX OF EXHIBITS

UPON COMMENCING AT 10:05 A.M., THIS SEVENTEENTH DAY OF AUGUST 2016 at the offices of Decision One, One Place Ville Marie, Suite 2901, Montreal, Quebec, Canada, H3B 0E9.

BY THE VIDEOGRAPHER: Good morning. We are now on the record. My name is David Oxilia. I am the Videographer representing Veritext Legal Solutions. This begins the deposition of Dr. Mark J. Eisenberg, M.D., M.P.H. in the case entitled Clare Austin versus C.R. Bard Inc. et al. This is case number 15-008373, Division 07. This deposition is taking place at Decision One in Montreal, Quebec, Canada on August 17, 2016. The time on the video monitor is 10:05 a.m. The Court Reporter today is Cherie Klein. Will Counsel please state their appearances for the record.

MR. ROTMAN: Steve Rotman for Plaintiffs.

MR. MANKOFF: Joshua Mankoff for Plaintiffs.

MR. JOHNSON: Joe Johnson representing Clare Austin.

MR. NORTH: Richard North

representing the Bard Defendants.
MR. BUSMAN: Phil Busman for Bard.
BY THE VIDEOGRAPHER: Thank you. The Court Reporter will now swear in the Witness.
WITNESS SWORN
DIRECT EXAMINATION
BY MR. NORTH:
Q. Good morning, Dr. Eisenberg.
A. Good morning.
Q. As I introduced myself earlier, my name is Richard North and I represent the Bard Defendants in this action. Today I am going to be asking you some questions about your work in this case and the opinions you may have reached since you have been designated as an expert Witness. If at any time I ask you anything that you did not hear or do not understand, please ask me to repeat it or rephrase it. Is that agreeable?
A. Yes.
MR. NORTH: And Counsel, I would also propose that we proceed with this deposition in accordance with the usual stipulations. It's being taken by agreement and by notice under the Florida Rules.

MR. JOHNSON: No problem.
BY MR. NORTH:
Q. And I would also ask, Doctor, that as you answer questions, try to avoid a nod of the head, or uh huh or uh uh, because it makes it difficult for the Court Reporter to create a transcript.
A. Understood.
Q. And you have been deposed before, haven't you?
A. Yes, I have.
Q. On how many occasions?
A. I can't say exactly. The last time, I believe, was five years ago or more, so I would have to go back and look.
Q. Have you ever testified in Court?
A. I have.
Q. On how many occasions?
A. Again, I would have to go back and look. The last time was at least five years ago.
Q. Do you think you have testified in Court as many as five times?
A. No, I don't believe so.
Exhibit 1 was marked for identification.

BY MR. NORTH:
Q. Doctor, let me hand you what's been marked as Exhibit 1, which is the Notice that was filed for your deposition. Have you seen this before?
A. Yes. Yes, I have.
Q. And if you would look at Exhibit A to the Notice, which is a list of the documents you were requested to bring, did you bring any of these items to the deposition today?
A. It was my understanding that all of these documents have been provided to you directly.
Q. So nothing was brought separately today?
A. The only thing I brought separately were a few handwritten calculations that I have here.
Q. And what sort of calculations are those?
A. These are sample size of power calculations and calculations of confidence intervals for studies of different sample sizes.
Q. Concerning what underlying data?
MR. ROTMAN: Objection.

THE WITNESS: I am sorry. Could you repeat the question?
BY MR. NORTH:
Q. You said these are calculations of sample sizes and confidence intervals. What data were you using to make these calculations?
MR. ROTMAN: Objection.
THE WITNESS: Well, the first set of calculations is just calculations of confidence interval sizes depending on various sample sizes, so not referring to any specific study. So I looked at different sample sizes, and different potential complication rates and looked at what size the confidence intervals would be around the point estimates and complication rates. So that would be the first set of calculations. The second set of calculations are sample size and power calculations, if one were to design a clinical trial comparing a predicate device with low complication rates and a newer device with higher calculation rates. And these calculations were calculating sample sizes for the two arms of the trial that would be required to look and identify the various differences that I presupposed.

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BY MR. NORTH:
Q. Okay.
A. The third set of calculations is again sample size calculations for clinical trials if one wanted to identify differences between a -- two different complication rates. And the complication rates that I was looking at came from the Grassi article.
Q. If I could see those just a minute. And we are going to have them marked as Exhibits with the understanding you can keep the originals and then we will make copies.
Exhibits 2, 3 and 4 were marked for identification.
BY MR. NORTH:
Q. Just so the record is clear, what we have marked as Exhibit 2 are the first set of calculations you described concerning confidence intervals.
A. Yes.
Q. What we have marked as Exhibit 3 is the second group of calculations you have just discussed, which deal with sample size for a projected clinical trial.
A. Yes.

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Q. And Exhibit 4 focuses on, as I understand it, sample sizes that -- for a clinical trial that would make comparisons between two different complication rates.
A. That's correct.
Q. Okay. Are those the only documents you brought with you today?
A. Yes.
Q. In looking at the previous cases that you have testified in as an expert witness, we were provided with a list of those and I am going to mark that as an Exhibit. It appears most of those cases were medical malpractice actions. Is that correct?
A. I believe that's correct, yes.
Q. We saw that you did testify as an expert in a multi-district proceeding against Bayer, the manufacturer.
A. Yes. I would have to refresh my recollection with that.
Exhibit 5 was marked for identification.
BY MR. NORTH:
Q. This has been marked as Exhibit 5, and this is an attachment to an interrogatory

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response provided by the Plaintiff in this case. Does that look to be a copy of your previous testimony list?
A. Yes.
Q. And the second from the bottom, what does that concern? I believe it's -- I can't say this -- Aprotinin?
A. Yes.
Q. That involved a drug or pharmaceutical product manufactured by Bayer Corporation, didn't it?
A. I believe so.
Q. Is that the only time you have testified in a case involving a pharmaceutical product or a medical device?
MR. ROTMAN: Objection.
THE WITNESS: Again, I would have to go through. This happened a while ago, so I would have to go through these again to say with assurance, but I believe so.
BY MR. NORTH:
Q. As you sit here today you cannot recall another case, other than the Bayer proceeding, in which you testified where there was an issue concerning a pharmaceutical product

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or a medical device?
MR. ROTMAN: Objection.
THE WITNESS: I don't recall being deposed or testifying, yes.
BY MR. NORTH:
Q. Okay. In your medical malpractice actions are you generally testifying on behalf of the Plaintiffs, or on behalf of the physicians or is it both?
MR. ROTMAN: Objection.
THE WITNESS: I have been consulted for both Plaintiffs and Defendants. I think most of the -- of the depositions and testimony were on behalf of the Plaintiffs.
Exhibit 6 was marked for identification.
BY MR. NORTH:
Q. Let me hand you what's been marked as Exhibit 6. Is that a copy of your curriculum vitae?
A. Yes, it is.
Q. And this one appears to be dated May 23rd of 2014, if you look at the bottom left-hand corner.
A. Yes, that's correct.

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Q. Do you have an updated one since then?
A. I do, and I believe that I --
MR. ROTMAN: I believe he has provided that to us and I understood that we had provided it to you. I am not sure, because I wasn't the one doing it. Joe?
MR. JOHNSON: I am not sure which one we provided. I assume whichever one we were provided was in turn provided.
MR. NORTH: My understanding is the one we were provided was from May 23rd of 2014, the one that has been marked as an Exhibit. We would ask that an updated c.v. please be provided to us.
MR. JOHNSON: Sure.
BY MR. NORTH:
Q. Now, you are a medical doctor?
A. I could e-mail you right now if that will assist you.
Q. Okay. You are a medical doctor?
A. Yes. I am a cardiologist and a clinical epidemiologist. So I am a medical doctor, yes.
Q. Do you consider yourself an

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interventional radiologist?
A. Well, I am an interventional cardiologist, so I am not an interventional radiologist but I do a lot of the same techniques that interventional radiologists do.
Q. Did you implant inferior vena cava filters as a part of your practice?
A. No, I have never implanted inferior vena cava filters.
Q. Have you retrieved inferior vena cava filters?
A. I have retrieved fragments of catheters from radiation but I have never retrieved an inferior vena cava filter.
Q. Have you ever implanted stents of any sort?
A. Yes, I routinely implant stents.
Q. What facility are you primarily associated with now?
A. The Jewish General Hospital, which is one of the McGill hospitals here in Montreal.
MR. ROTMAN: Off the record.
---(OFF-THE-RECORD DISCUSSION)---.
BY MR. NORTH:
Q. Doctor, at McGill, at your hospital

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are you part of an interventional cardiology group?
A. Well, there is a group of us interventional cardiologists, but we are a sub-set of a general cardiology group.
Q. Are there other interventional cardiologists in your group that implant inferior vena cava filters?
A. No.
Q. Are there interventional radiologists at your hospital that implant filters?
A. Yes, we have interventional radiologists that implant filters at our hospital.
Q. Do you know what brand of filters they are presently implanting?
A. If I am not mistaken, they are implanting a variety of filters, so I can't tell you which ones, but it's not just a single brand.
Q. Do you know if they are presently implanting any Bard filters?
A. I do not know that.
Q. I believe you said you were both an interventional cardiologist and a clinical

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epidemiologist.
A. Yes, I am.
Q. Define for us what a clinical epidemiologist is.
A. Well, I have a masters of public health degree from Harvard where I studied biostatistics and epidemiology as well as other topics. So I spent half my time doing clinical cardiology, including interventional cardiology, and I spent half my time doing research. And the research that I do is clinical epidemiology research, so that involves clinical trials, systematic reviews, meta analyses, cohort studies as well as a variety of other methodologies that are within the rubric of clinical epidemiology.
Q. Have you ever been the lead investigator of a clinical trial?
A. I have.
Q. On how many occasions?
A. I believe five clinical trials.
Q. Generally what did those clinical trials involve?
A. I did two clinical trials with patients who had percutaneous coronary interventions -- among patients who had

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angioplasty, and they were randomized to routine stress testing versus a more conservative strategy, and then they were followed up to see if more intensive stress testing strategy made a difference in outcomes. I did a clinical trial for patients with non-QA myocardial infarctions, and they were randomized to an invasive strategy versus a conservative strategy to see which one had better outcomes. I did a clinical trial in patients who had acute coronary syndrome or myocardial infarctions and who were smokers, and they were randomized to Bupropion, which is an anti-smoking medication. They were randomized to Bupropion versus placebo, and then they were followed up to see if that had any impact on their smoking cessation rates. I did another trial that took patients with acute coronary syndromes that were smokers, and the patients were randomized for Varenicline versus placebo, again to see the impact on smoking cessation rates. I am involved in a trial which we are just starting now. It's been funded and we are just about to start randomizing with smokers being randomized to electronic cigarettes, with or without nicotine, as well as counselling to

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see if that has an impact on smoking cessation rates.

Q. Have you ever conducted a clinical trial about a medical device?

A. I don't think that I have ever been a lead investigator of a clinical trial where patients were randomized to a medical device versus not.

Q. Have you ever been an investigator in such a trial, even if you were not the lead investigator?

A. No. As you know, I routinely implant stents. Some of those -- some of those patients that received stents were collected in the form of a registry, but again I was not the lead investigator. I have also been involved in other clinical trials as a collaborator, again not as a lead investigator, for example, drug trials where patients were randomized for one drug versus another.

Q. Other than the experience with clinical trials or registries actually and stents, have you ever been involved as an investigator in a clinical trial involving a medical device?

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A. Well, I have never been the lead investigator for a clinical trial involving medical devices, but I actually have quite a number of publications related to medical devices. One of the areas that I am involved with and interested in research-wise is technology assessments. So we have done technology assessments on different medical devices over the years, done some cost-effective analyses as well involving medical devices.

Q. Have you ever published anything concerning inferior vena cava filters?

A. No, I have not.

Q. Prior to your retention as an expert in this litigation, have you ever had any professional involvement with inferior vena cava filters?

MR. ROTMAN: Objection.

THE WITNESS: Well, sir, although I am an interventional cardiologist I am also a general cardiologist, so I am routinely involved in the diagnosis of patients with deep vein thrombosis and pulmonary emboli. And some of those patients I refer on to thrombosis experts and eventually those patients, some of them get

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inferior vena cava filters. And also in the cath. lab I am doing angiograms. Our centre is a centre of excellence for pulmonary hypertension, so I do a lot of right and left heart cath's. So the left heart cath's are the ones where we are putting stents in the coronaries. But I am routinely putting catheters in the inferior vena cava to go into the right atrium, the right ventricle pulmonary arteries to measure pressures and do pulmonary angiograms. As well I do at our hospital -- it's usually done by radiologists at other hospitals. But I would like to say that some of my patients that come to the cath lab have inferior vena cava filters, so I cannot put a catheter into the inferior vena cava to do my studies, so then I would have to go through the superior vena cava, through a jugular vein to do the studies.

BY MR. NORTH:

Q. Is it fair to say that your professional involvement with inferior vena cava filters has been observing the filters in your patients or treating patients that ultimately would receive the filter?

MR. ROTMAN: Objection.

THE WITNESS: Yes. I think the majority of my exposure to inferior vena cava filters is in situations of diagnosing patients who eventually require filters or my patients who have filters in place, yes.

BY MR. NORTH:

Q. But in your practice you are not the person that makes the recommendation for an inferior vena cava filter to be implanted in a patient; correct?

A. Typically not, but that would happen occasionally that it was a clear-cut case of a patient who needed a filter and I would refer them directly, but it would be unusual.

Q. Can you recall the last time you referred a patient to have an inferior vena cava filters implanted?

A. Well, I was just rounding in CCU two weeks ago where we had a patient who came in with a DVT pulmonary emboli and had a pericardial infusion which needed to be drained, and they needed anti-coagulation, but they are at high risk because of the drain. So I think this patient will ultimately get an inferior vena cava filter. I did not refer them for it. I think

they were not quite ready for it. And this would be a case where if the drain had been pulled from the pericardial sac we would have referred directly for an inferior vena cava filter.

Q. But that has not happened with that particular case as yet?

A. Well, I don't know after I left the CCU whether that's happened yet or not.

BY THE VIDEOGRAPHER: Going off the record at 10:28 a.m.

BY THE VIDEOGRAPHER: Going back on the record at 10:48 a.m.

BY MR. NORTH:

Q. Doctor, before we took that break, we were talking about your involvement as a physician in referrals of patients of implants of inferior vena cava filters, and I believe you told us you had done that before.

A. Yes.

Q. So do you believe that inferior vena cava filters are an appropriate treatment in some patients?

MR. ROTMAN: Objection.

THE WITNESS: I think that they are -- there is a group of patients who either cannot

be anticoagulated or they are resistant to an anticoagulation, and they would benefit from inferior vena cava filters.

BY MR. NORTH:

Q. And you have made that determination for some of your patients over the years?

A. Yes.

Q. Do you make any recommendations when you are referring a patient for an inferior vena cava filter between permanent filters and retrievable filters?

MR. ROTMAN: Objection. Can I hear the question again?

THE WITNESS: Yes.

QUESTION WAS READ BACK.

MR. ROTMAN: Same objection.

THE WITNESS: No, I mean, I am obviously aware of the differences between the retrievables and the permanents, but I am typically not giving recommendation about which filters should be put in. In our hospital we fortunately have a thrombosis service that usually takes care of these patients, so they are typically the ones that would make those determinations in conjunction with the

interventional radiologists.

BY MR. NORTH:

Q. So you defer to those fellow professionals to make that determination?

A. Typically; yes, I do.

Q. Doctor, how much do you charge for your consulting work for your work as an expert witness?

A. I charge $700 an hour.

Q. Does that charge differ depending on whether you are simply reviewing materials versus giving testimony?

A. It's $700 an hour for reviewing materials and teleconferences and meetings. I charge $1,100 an hour for depositions and testimony.

Q. Do you charge for your travel when you travel to give testimony?

A. Well, I haven't done that for a long time, so I have to go back and look and see what I did. If I am not mistaken, I had sort of a minimum charge.

Q. Do you have a minimum number of hours that you charge for a deposition?

A. No.

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Q. Do you have a minimum number of hours that you charge for a day of trial testimony?

A. Again, I haven't done this in a while, so I would have to go back and see. If I was to take a day off of work and travel somewhere and only testify for one hour, I probably would have to have some kind of minimum.

Q. Can you estimate for me how many cases you have presently that you are consulting on on litigation?

A. I mean, I guess I have to say, I don't know if --

MR. ROTMAN: So the question, just so that we are staying clear of areas where information is protected from Discovery, the question is just for a number, not to identify anything beyond a number. So can you re-read the question?

QUESTION WAS READ BACK.

THE WITNESS: I believe the answer to that would be two, including this one.

BY MR. NORTH:

Q. Okay. Is it fair to say that litigation consulting is a small percentage of your professional time?

A. Yes, it's the case.

Q. Would you say less than ten percent?

A. Yes, I would.

Q. And the same would be true as far as income. Income generated from litigation consulting is a small percentage of your income?

A. I am not sure -- how does that differ from your previous question.

Q. Well, time versus income?

A. I see. Well, both income and the time is very small compared to my regular job.

Q. Under ten percent in both instances?

A. Yes, I think that's correct. I am sure that's correct.

Q. Who were you first contacted by concerning filter litigation?

A. If I am not mistaken, it was Ramon Lopez.

Q. And how long ago were you contacted by Mr. Lopez?

A. If I am not mistaken, that would be 2013.

Q. Have you had -- well, in preparation for the deposition today, did you have any meetings with Counsel?

A. Yes, I did.

Q. And who was that with and when was that?

A. I met yesterday afternoon with these three gentlemen.

Q. For the record, Mr. Rotman and Mr. Mankoff and Mr. Johnson?

A. That's correct. And then last week I also met for half a day with Mr. Rotman and Mr. Mankoff.

Q. On how many prior occasions -- well, have you ever met with Mr. Lopez regarding filter litigation?

A. I have met with Mr. Lopez. I don't recall how many times. I think maybe twice.

Q. Were both of those occasions here in Montreal?

A. Yes.

Q. Prior to the meeting last week, had you ever met with Mr. Rotman or Mr. Mankoff before?

A. Not about this Austin case.

Q. Prior to yesterday had you ever met with Mr. Johnson before?

A. Again, not related to this Austin case.

Q. Can you estimate for us how much time you have spent in preparing and working with the Austin case?

A. Well, I think I -- you have copies of my invoices.

Q. Your invoices tell us nothing. Everything is blacked out.

MR. ROTMAN: For the record, that's inaccurate. You are asking for the amount of time, and that is not blacked out on the invoices.

MR. NORTH: We cannot tell. Well, we cannot tell from those invoices whether the time was spent with Austin or another case. So no, they do not tell us.

BY MR. NORTH:

Q. Can you estimate for us how many hours you have spent on the Austin case?

A. I think that -- at the time of that invoice I think it was approximately 20 hours and then since then perhaps 30 hours or less.

Q. So you are estimating 50 hours on this case?

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A. Yes.

MR. NORTH: And for the record, Counsel, we are going to reserve the right to reconvene this deposition because of what we consider a frivolous redaction of invoices and -- once we challenge that with the Court.

MR. ROTMAN: We reserve the right to object.

BY MR. NORTH:

Q. What Attorneys retained you in the litigation against Bayer?

A. I don't recall exactly. I would have to refer back to my document here.

Q. There is a mention on the listing of a Ronca under Lawyers.

A. Yes, I recall Jim Ronca. I don't recall if there were any other Lawyers that were involved.

Q. Have you ever worked with any of the Lawyers you are working with before -- or working with with regard to this Austin case, have you worked with them on any previous litigation, other than filter litigation?

A. I don't believe I worked with Mr. Mankoff or Mr. Rotman before. Joe Johnson, I

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believe we met before. I don't recall if that actually led to litigation or not, and I don't recall what the topic was either.

Q. Well, prior to your involvement in the filter litigation with Mr. Lopez, had you worked with him on any consulting matter?

A. Not to my recollection. But for example, the Aprotinin, there were often many Lawyers involved, so I don't recall who was involved.

Q. In looking through your c.v., it appears you obtained your medical degree from the University of Rochester School of Medicine.

A. Yes, that's correct. I graduated there in 1985.

Q. And your c.v. seems to suggest you took a break from your studies.

A. While I was I medical school; yes, I did. I took a year off.

Q. What did you do during that year off?

A. I went to Israel for the year, and then I spent six months in an intensive Hebrew course and then I did research in a hospital in Jerusalem. I think it's listed on my c.v. under

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a different section, if I am not mistaken.

Q. In 1994 and 1995 you have listed an interventional fellow at Cleveland Clinic. Could you tell me what that was about?

A. Yes. I mean, after medical school I came to Montreal and did my internal medicine at McGill and I also did a masters of public health at Harvard and I was overseas for a year, but then I did my cardiology training in San Francisco, so I had matched in an academic cardiology program. So it was two years of research and two years of clinical cardiology, and then finally one year interventional cardiology fellowship at the Cleveland Clinic. So that was July '94 to July '95, and that was learning how to do angioplasty.

Q. Doctor, do you know what the predicted annual rate of occurrence of pulmonary emboli each year is in either Canada or the United States?

MR. ROTMAN: Objection.

THE WITNESS: Well, I didn't review that literature in preparation for this deposition, so I would be reluctant to give you a number.

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BY MR. NORTH:

Q. I believe you mentioned earlier that there is a thrombo -- what did you call it?

A. Thrombosis.

Q. Thrombosis group in your hospital. As a consequence, are you not the primary treating physician of patients that are being treated for pulmonary embolism?

A. I am the primary treater for some patients and other patients are primarily treated by the thrombosis team. Oftentimes they will initiate therapy and then the patient will be followed by me in clinic. So we have all different variations there.

Q. Do you generally prescribe anticoagulants as a part of your practice?

A. Yes, I do.

Q. Which ones do you generally or predominantly prescribe?

A. Well, I prescribe Coumadin. I prescribe novel oral anticoagulants like Apixaban, Rivaroxaban.

Q. What do you mean by the use of the word "novel" in that context?

A. Well, "novel" is a bit of a

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misnomer. They started calling them novel when they first came out. They have been out for a while. They have been out long enough now that they are no longer novel, but we still use that term. They are also known as NOACS. N-O-A-C-S. These are alternatives to coumadin that can be taken orally and they don't require any medical monitoring in terms of blood testing like coumadin does.

Q. Have you ever had a patient where you believe an inferior vena cava filter actually saved the patient's life?

A. Not to my recollection, but oftentimes it might has been and you would not realize it.

Q. Have you ever had a patient that has suffered from an adverse event related to an IVC filter?

A. In my personal practice I do not believe I have ever had anybody with a complication that I have been made aware of.

Q. You seem to be limiting that to your personal practice. Have you had contact with patients that you know had adverse events related to IVC filters?

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A. I am aware of complications from the medical literature, but I have not seen a patient directly that had a complication related to IVC filters.

Q. So you have never had personal contact with a patient who has had a fracture or migration of an IVC filter, to your knowledge?

MR. JOHNSON: Objection.

THE WITNESS: Not to my recollection.

BY MR. NORTH:

Q. What is the average size of an individual's IVC?

MR. ROTMAN: Objection.

THE WITNESS: I don't know what the average size is of an individual's inferior vena cava, but I know that the Bard filters were indicated for patients with an inferior vena cava diameter of 28 millimetres or less.

BY MR. NORTH:

Q. Do you have any information about the range of sizes of the typical human IVC?

A. I did not look at that literature. I mean I didn't look at the literature regarding IVC sizes. I also know it's a dynamic structure,

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so depending on whether a patient coughs or their position changes, whether they are -- I am very aware -- in cardiology we are very aware of patients, if they are dehydrated or that the inferior vena cava is smaller, or if they are in right heart failure it's dilated. If they have an acute pulmonary embolus it's dilated. So we are very aware of the diameter changing. That's why we use that clinically, but in terms of measuring the actual diameter, that's not typically what we do.

Q. Do you know what sort of complication, if any, Ms. Austin alleges?

MR. ROTMAN: Objection.

THE WITNESS: I believe that she had a filter tip, and perforation and fracture, migration of pieces of the filter into -- if I am not mistaken, into the pancreas and I think into the spine as well.

BY MR. NORTH:

Q. Have you reviewed any of her medical records?

A. I have not reviewed any of her medical records. I believe I saw a few lines describing her medical case.

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Q. You have not spoken with any of her treating physicians, have you?

A. No, I have not spoken to any of her treating physicians.

Q. Do you know whether her filter has been removed?

A. If I am not mistaken, her filter has been removed. But again, I didn't have access to any of her direct medical records.

Q. Do you know what model filter she had placed?

A. I believe she had a G2 filter that was placed.

Q. Before your involvement in the filter litigation, were you aware of Bard filters specifically?

A. I had heard of them. I had heard of the various filters. I was not -- I mean, I peripherally was aware of the literature, but not to the extent that I am now.

Q. Prior to your involvement in filter litigation, were you aware of the differences between the Recovery filter and the G2?

A. I knew the names. I wasn't aware of the exact differences between them.

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Q. Before your involvement in the filter litigation, were you aware of any differences between the G2 and later generation Bard filters?

A. Again, I was aware of the names of the filters, but not the specific differences between the different generations.

Q. Prior to your involvement in this litigation, had you ever heard of the Simon Nitinol filter?

A. I had heard of that.

Q. Do you know whether you have had involvement with any patient that had a Simon Nitinol filter placed?

A. I can't say that. Again in cardiology, is there a filter: Yes or no. So I wasn't aware of the different models that were put in.

Q. Do you know whether the interventional radiology group in your hospital implants Simon Nitinol filters?

A. I do not know that.

Q. Do you know whether they have in the past?

A. Again, I am not aware of what models

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they have placed. I am confident they have placed more than one model and they have over the years, but I can't tell you exactly which ones.

Q. So you do not know one way or another whether the interventional radiology group at your hospital either has placed in the past or presently places Bard filters?

A. No, I can't say that, that I know with assurance that they have placed Bard filters. I would suspect that they have but I don't know for sure.

Q. We can agree you are not an engineer; correct?

A. I am not an engineer.

Q. And you are not a metallurgist?

A. I have no training of metallurgy.

Q. Have you ever been involved in the design of a medical device?

A. I can't say that I have been directly involved in the design of a medical device.

Q. Have you ever worked with the United States Food and Drug Administration?

A. I haven't worked with them. Can you repeat that question, please?

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Q. Have you ever worked with the United States Food and Drug Administration?

A. Well, I have never worked for the FDA. I have had some communications with the FDA over one of the clinical trials that I did. They called me and I gave them information.

Q. Other than communications --

MR. ROTMAN: Are you done with the answer?

MR. NORTH: Sorry?

MR. ROTMAN: Were you done with the answer?

THE WITNESS: I have also done submissions to the FDA for some of our clinical trials to be done in the U.S. as well as Canada.

BY MR. NORTH:

Q. You haven't done any submissions to the FDA seeking approval for a pharmaceutical or medical device, have you?

A. I haven't done any seeking approval for a medical device. For drugs I -- again, I went to the FDA to seek approval to do a clinical trial with a non-label indication, but it was not for a new drug.

Q. Have you ever done any work with

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Health Canada?

A. Yes, I have done some work with Health Canada, again in the same context of getting approval to do clinical trials.

Q. Would you consider yourself an expert in the regulations of the FDA or Health Canada?

A. No, I can't construe that I am an expert with regulations for either the FDA or Health Canada.

Q. Would you consider yourself an expert in pharmacovigilance?

MR. ROTMAN: Objection.

THE WITNESS: Can you repeat that question, please?

BY MR. NORTH:

Q. Would you consider yourself an expert in pharmacovigilance?

A. Well, although I wouldn't consider myself an expert in pharmacovigilance, I believe I have a lot of training in that area, certainly much more so than the typical clinician. I mean, a lot of the research I do involves drugs, and drug complications and database research. So although I can't say that I am an expert in

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pharmacovigilance, I am pretty comfortable with many of the issues in that area.

Q. In your work in the litigation against Bayer you were furnished and you reviewed some internal Bayer documents, didn't you?

A. Yes, I believe I did.

Q. And in this litigation you have been furnished and reviewed some internal Bard documents. Is that correct?

A. Yes, I have been given some internal Bard documents for review.

Q. Other than your involvement in these two litigations, the Bayer litigation and the Bard filter litigation, have you ever had an occasion, as a part of your professional work, to read and analyse internal documents from a pharmaceutical or medical device manufacturer?

A. I don't recall exactly, but it's possible that there were one or two other situations where I saw internal documents from a company that was more an exploratory phase and never reached deposition or testimony. I am not even sure whether the litigation was pursued. But again, this is recollection.

Q. And what you are talking about

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there, the other instance that may have happened, that would have been litigation-related; correct?

A. I think there were situations where there is a possibility of litigation or where they were exploring the possibility of litigation, but I don't know if it actually proceeded or not. I am not even sure that I saw internal documents at that time.

Q. Well, is it fair to say you have not had occasion to review internal manufacturer documents as part of your professional work outside of your consulting practice?

MR. ROTMAN: Objection.

THE WITNESS: It's unusual for me to review internal document from companies. I do -- as I had mentioned earlier, I am doing a clinical trial on electronic cigarettes and, as part of that trial, we had to go through Health Canada and we are working with a company in the U.S. that produces the electronic cigarettes. So I have had access to some of their internal documents and some of their internal testing that had to be provided to Health Canada. So in that context I had seen some documents -- internal documents from a pharmaceutical -- not a

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pharmaceutical company but a device company. I am not sure that I have seen internal documents in other situations other than that.

Q. I mean, you don't look at internal corporate documents as a part of your work as a cardiologist at Jewish Hospital, do you?

A. That's not a typical part of my -- no. If I did, it would be very small, but I am not sure that I see any.

Q. And you don't consider yourself an expert in corporate ethics, do you?

A. No, I can't say that I am an expert in corporate ethics.

Q. Do you know what division of the FDA regulates IVC filters?

A. I would have to -- I would have to go back and review my documents to tell you the answer to that.

Q. So as you sit here today you can't tell me?

A. I don't recall.

Q. Do you know how the FDA defines a safety signal?

MR. JOHNSON: Form.

THE WITNESS: Again, I would have to

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go back to their documents or website in order to give you the exact definition they use.

BY MR. NORTH:

Q. Have you ever seen in the past, that you can recall, documents or regulations where the FDA has defined a safety signal?

A. I don't recall offhand. It's quite possible that I have seen that.

Q. Have you ever made a report to the MAUDE database at the United States FDA concerning an incident or complication involving a medical device?

A. I have not made a direct submission to the MAUDE database myself.

Q. Have you -- well, have you ever directed somebody that works with you or for you to make such a report?

A. I don't recall ever doing that.

Q. Have you ever reported a complication with a medical device to Health Canada?

A. Sorry? Can you repeat that question, please?

Q. Have you ever reported a complication involving a medical device to Health

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Canada?
A. Offhand I don't recall doing that. I was involved when I was training here in Montreal, being involved in a report -- there was -- this is not a medical device, but there was an epidemic from mussel poisoning, so that was a reportable event that I was involved in.
Q. Other than that, can you recall making a report to Health Canada regarding a complication involving a medical device?
A. Offhand I don't recall doing that.
Q. Are you aware of the fact that Health Canada recently issued a public health notification regarding inferior vena cava filters?
A. Yes, I did see that. That was circulated at McGill.
Q. Did you have any consultation with Health Canada about that issue prior to the release of that notice?
MR. ROTMAN: Can I have the question again?
QUESTION WAS READ BACK.
THE WITNESS: Do you mean have I received other notices from Health Canada?

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BY MR. NORTH:
Q. No. I am asking concerning the notice regarding IVC filters. Did you consult with Health Canada about that topic prior to their issuance of that notice?
A. No, I have not had any contact with Health Canada about IVC filters.
Q. You are not an expert in medical device labelling, are you?
A. No, I cannot say that I am.
Q. When you implant medical devices do you generally review the instructions for use?
A. I typically do when I first use it, yes.
Q. You have no education or training specific to medical device labelling, do you?
A. No, I don't have any specific training.
Q. You have never drafted the label for a medical device?
A. No, I don't believe I have been involved in drafting labelling for medical devices.
Q. And have you ever worked directly for a medical device company as a consultant?

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A. I don't believe that I have been a consultant to a medical device company, but I have been members of advisory boards for pharmaceutical companies. It's possible that I was -- you know, attended one or two meetings for advisory boards for medical devices, but again I don't recall.
Q. Have you ever had any contact with Bard prior to your involvement in this litigation?
A. Not to my knowledge.
Q. What sort of advisory boards for pharmaceutical companies have you served on?
A. Well, the advisory boards that I have served on have been in very limited capacities. So these are typically when they gather a small group of physicians together that use a particular medication to get feedback on whether the medication is effective, safe, marketing issues. But really I would say I have done that only on a handful of occasions.
Q. Do you remember which pharmaceutical companies?
A. I was on the advisory board with Phizer for Varenicline for a couple of years

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which involved, I believe, a yearly meeting. I probably went to two meetings. And then I, you know, decided to get off the board. I have been to a couple of advisory board meetings recently which I believe was with Bayer regarding one of their anticoagulants, but really I would say I have been to a very small number of advisory board meetings. These are not ongoing commitments.
Q. Do you know Dr. Betensky who is another expert in this case?
MR. ROTMAN: Objection.
THE WITNESS: I have never met her personally. I know of her.
BY MR. NORTH:
Q. Have you spoken with her on the phone?
A. I have.
Q. On how many occasions?
A. I believe I spoke with her twice.
Q. Have you reviewed her deposition taken in the Austin case?
A. I don't believe I reviewed her deposition.
Q. Have you reviewed any of her

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calculations?
A. I have reviewed her calculations and was provided with a spreadsheet that I believe she prepared.
Q. Did you try to recreate her calculations?
MR. ROTMAN: Objection.
THE WITNESS: I am sorry. Can you repeat that?
BY MR. NORTH:
Q. Did you attempt to recreate her calculations?
A. Well, I had her spreadsheet, and the purpose of these two telephone calls were for me to ask questions about her spreadsheet and how she generated these numbers so I could understand the types of calculations she did. So I -- I am quite confident I understand how those numbers were generated.
Q. That was not my question, Doctor. Did you independently recreate her calculations?
MR. ROTMAN: Same objection.
THE WITNESS: I did not independently recreate her calculations but I am quite confident I understand how they were done,

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and they were done appropriately.
BY MR. NORTH:
Q. Other than the calculations that you showed us earlier concerning confidence levels and sampling sizes for potential clinical trials, those three pages of calculations, have you performed any other calculations in this litigation?
A. No, I don't believe I have.
Q. Let me hand you what's been marked as Exhibit 7.
Exhibit 7 was marked for identification.
BY MR. NORTH:
Q. Which is a Discovery Response filed by the Plaintiffs in this case. Have you ever seen that before?
A. I believe that I saw this document previously, but I had asked it be amended, so I believe there was another version of it after this one.
Q. Turning to page six, that's where the discussion -- the description of your view begins; correct?
A. Yes, this is a section about my --

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some of my views.
Q. Can you tell me what parts of this you asked to be amended or revised?
A. Well, I can't recall exactly, but I recall specifically on page two much earlier that, although I have training in biostatistics and I use them on a daily basis and am very comfortable with them and work with biostatisticians, I would not call myself a biostatistician, so I thought that that should be removed. And I thought that -- I call myself a clinical epidemiologist rather than a epidemiologist. A clinical epidemiologist, I believe, works on clinical issues and uses epidemiological methods to look at clinical issues, whereas epidemiologists typically are more dealing with traditional epidemiology with risk factors which are much closer to the patient than that. And also in that same section I asked to remove the sections about rates of pulmonary embolism mortality rates because I didn't specifically review that literature for this case. So those are some of the things that I had asked to be revised. I don't recall if that was all of them.

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Q. It's fair to say that the descriptions or summaries of your testimony in this document were not originally drafted by you; correct?
A. Which sections are you referring to?
Q. Both sections that mention you, the one on page two and the one beginning on page six.
A. I think that these sections were drafted in consultation with me and also with reference to my c.v.
Q. That's not my question. Did you personally put pen to paper for the original drafts of these?
A. I did not put pen to paper to write these sections.
Q. I guess in this age I shouldn't limit it to pen and paper. You didn't personally type the initial draft of these; right?
A. I don't believe that I did.
Q. Do you -- have you ever seen a version of the paragraph about you on page two that was revised in accordance with your requests?
A. Yes, I have.

Q. Did you make any revisions to the section that begins on page six?

A. I don't recall if I had asked this to be revised. Certainly, in re-reading this, there is clearly a typo on the bottom of page six where it says he is expected to testify that the Asch study and Everest study on retrievability were safety or efficacy studies -- it should be that they were not safety or efficacy studies and they were not designed to function as safety or efficacy studies, so there is missing a "not" there, although I don't recall if I had actually asked that to be revised.

MR. ROTMAN: I don't think he is done reading the rest of the section. There may be more.

THE WITNESS: That's all I recall at this time for that section.

BY MR. NORTH:

Q. In the litigation involving the Bayer drug, you prepared a lengthy expert report, didn't you?

A. Yes, I did.

Q. And you wrote that report yourself, didn't you?

A. Yes, I prepared it myself.

Q. But for this particular case you have not prepared a report, have you?

A. No, I have not.

Q. Since you did not prepare a report and you did not initially draft this description of your testimony, could you list for me what your principal opinions are in the Austin case?

MR. ROTMAN: Objection.

MR. JOHNSON: Objection.

THE WITNESS: I think that would be -- I mean, I could list some of my opinions. I have a large number of opinions. I haven't written them out. I am sure I would miss some. Could you ask me specifically about particular opinions?

BY MR. NORTH:

Q. Doctor, you have not furnished a writing of your opinions that you drafted. We are entitled under the procedural rules to take this deposition and ask you your opinions. So my question to you is: Can you tell me generally what your opinions are in this case?

MR. ROTMAN: Objection.

MR. MANKOFF: Objection.

THE WITNESS: I am sorry. Can you repeat the question?

BY MR. NORTH:

Q. Can you tell me generally what your opinions are in this case?

A. I can give you a couple of my general opinions, and then there will be a whole lot of specific opinions under that.

Q. Okay. Let's start there.

A. My general opinion is that there is a high rate of complications with both Recovery in the G2, G2 Express filter compared to the Simon Nitinol filter; that there are a variety of complications associated with these retrievable filters that are more common with them than their predicate device that was the SNF; further that there were multiple early safety signals with these devices and these safety signals include safety signals seen from the MAUDE database which is known internally to Bard. There was also an extensive medical literature documenting elevated complication rates with retrievable filters, and then there was also some Bard internal documentation about low migration resistance with the retrievables compared to the permanent. So

-- and I believe there was -- Bard had a consultant that brought these issues to the attention of Bard and that Bard --

Q. Doctor, I would ask you not to talk about this consultant. There is an agreement in this case that that is privileged and there are rulings in other cases that that is privileged, so I don't want that on the Record, a discussion of this consultant. You can continue.

MR. MANKOFF: There is a reference to the consultant in the HHE.

THE WITNESS: Yes, that's what I am referring to.

BY MR. NORTH:

Q. Okay. What that understanding, yes.

A. Okay. So I am referring to that HHE which refers to the consultant's findings, that there were complication rates on the order of four or five times more common among Recovery filters compared to the predicate device.

Q. Okay. Continue.

A. So my opinion is that Bard -- it was their responsibility to do large safety and efficacy studies in order to address these concerns and that these safety studies were never

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done. I believe that Bard recognized that there were increased complications with Recovery. They had -- I don't recall the exact term, but they had a crisis or a crisis evaluation plan. There was a hold put on -- a commercial hold for a short while with Recovery, but then the G2 was developed to overcome the complications associated with Recovery, and so Recovery was removed from the market and G2 was put on the market, again without large safety and efficacy studies. And again, there was data from the MAUDE database and from migration testing, from medical literature that there were high complication rates associated with G2. So again the device was redesigned and released as another iteration of device. So I guess my overall opinion is that there are increased complication rates associated with retrievable devices compared to the predicate device. There were signals from at least three different lines which suggested this, and yet the company did not pursue looking at these safety signals as they should have.

Q. Okay. The first thing you told me --

MR. ROTMAN: Can you just make sure

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he was done with his answer?

THE WITNESS: Yes, I guess I would like to add to that, which is that I think that -- from their internal documents it was clear that Bard recognized that there were elevated complication rates that were alarming or concerning and they were concerned that physicians were stopping to use their device and that they were -- I mean, that they had reports of multiple interventional radiologists who were stopping to use Bard devices. So there were some instructions given to the sales team how to -- I would call it spin control, but to put this in context, and they were comparing the MAUDE rates to the rates in the Grassi article, which really is comparing apples and oranges which I think is an inappropriate comparison and misleading. I am looking through my list of opinions here. I think that's it for my general opinions. It's possible I missed a few.

BY MR. NORTH:

Q. Doctor, can you tell me anything specifically that you were taught in your training in medical school that gives you special expertise in reviewing Bard's company documents

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and making determinations as to what the company knew or did not know?

MR. MANKOFF: Form.

MR. ROTMAN: Objection.

THE WITNESS: Well, I don't have specific training looking at company documents and identifying what the company knows or doesn't know, but I will say first of all, as a clinician who puts devices in patients and as a clinician who takes care of patients with these devices implanted, if the kind of information I was seeing in the company documents was not provided to me I would be very unhappy. I think that -- if I or someone in my family had a device implanted and within the company documents they were reporting rates, you know, four times greater of complications than another device, I would want to know about it. I wouldn't want that device in me or in my family member. Certainly as a clinician taking care of those patients, that would be very relevant information for me to know. So -- and then I think that you

[redacted]

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[redacted]

BY MR. NORTH:

Q. Doctor, one of the first things you told me is that you have the opinion that there was a high rate of complications with the Recovery filter and the G2 when compared with the Simon Nitinol filter; correct?

A. Yes, I believe that's what I said.

Q. And on what did you base that? On what data?

[redacted]

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[redacted]
retrospective study of all the IVC filters that were placed in our institution. They published the paper and documented high rates of complications. Other studies were prospective studies, prospective registries, such as the Asch study or the -- what, I guess, you guys term the Everest study which the first author was Binkert, looking at G2. So there are a whole host of medical studies in the medical literature, looking at complication rates among the retrievable filters.

Q. Did the Asch -- -

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MR. ROTMAN: Were you done?

THE WITNESS: In addition to that there were also a large number of case reports of complications associated with IVC filters that appeared in the literature and while, you know, case reports on their own can't really tell you a rate of complication, they indicate that physicians were seeing complications that they had not seen before, and felt impelled to report them in the literature so other physicians would be aware of this. I -- I also read the deposition by Murray Asch, and I read his article where he was doing the retrievability study on Recovery filters and found that there were complications in his first 33 patients. He had two major complications that he found that he felt that he had been misled by the company and that he felt that the company was just using this -- was supposed to use this as a pilot study and that a further large study would be done afterwards.

MR. NORTH: I object to the responsiveness of the answer.

BY MR. NORTH:

Q. Are you finished?

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A. I believe I am finished.

Q. Can you name me some of these medical studies that you believe support this opinion that the complication rate of the Recovery filter and the G2 are higher than that the Simon Nitinol filter?

A. I am sorry. Can you repeat that question, please?

Q. Can you name me some of the medical studies that support your opinion that the complication rate of the Recovery filter and the G2 is higher than that of the Simon Nitinol filter?

A. Well, there is a large number. I can name you a couple of them: The Kalva study. There is Nicholson. There is an Asch study. There is the Binkert study. So those are just a few of them.

MR. ROTMAN: Can we take another break? Ask another question and take a break?

MR. NORTH: Let me ask another question.

BY MR. NORTH:

Q. Were there any complications reported in the Binkert study?

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A. Yes, there were.

Q. Do you recall what those were?

A. I would have to see a copy of it to refresh my memory.

MR. NORTH: Okay. Let's take a break.

BY THE VIDEOGRAPHER: Going off the record at 11:49 a.m.

BY THE VIDEOGRAPHER: This begins disk number two in the deposition of Dr. Eisenberg. We are going back on the record at 12:05 p.m.

BY MR. NORTH:

Q. Before we took that break we were talking about some of the medical literature, and you were listing for me some of those that you believe supported your opinion, and one of those you mentioned was a Nicholson article.

A. Yes.

Q. Did the Plaintiff's Attorneys provide you with the deposition that's been taken in filter litigation of Dr. Nicholson?

A. I don't believe so.

Q. Did they provide you with a copy of the clarification published regarding his

article?
A. I had seen that clarification on the web.
Q. Are you familiar with any of the criticisms of how he conducted that study?
MR. JOHNSON: Objection.
THE WITNESS: Well, I am -- I read many papers in preparation for today, and I am aware that every study has potential limitations. Specifically for that study, you know, the additional piece I read, I believe that was the article that had an editorial connected to it by Rita Redburn, if I am not mistaken, in the Archives of Internal Medicine, but that didn't really criticize the paper, as I recall.
Q. So the answer is you don't recall any specific information about criticisms of this study?
MR. JOHNSON: Form.
THE WITNESS: No, I do not recall that. I think that in many medical journals, if there is a paper it may be accompanied by an editorial, and many times the editorialist will put the paper in context but also discuss potential limitations. But I didn't see anything

to that effect for the Nicholson paper.
BY MR. NORTH:
Q. Did you provide any meta analysis in this case?
A. I did not do any pooling of data from different studies in this case. I have done many meta analyses in my research career, as you can see from my cv, but I have not done a meta analysis for this case.
Q. In this particular case all of the company documents that you have reviewed were furnished to you by the Plaintiff's Attorneys; correct?
A. Well, are you talking about the Bard internal documents?
Q. Right.
A. The Attorneys did provide me with a whole list of Bard internal documents that was shared in a Drop Box account. I actually picked and chose documents to look at because there were so many of them, so I can say that I didn't go through all of them. I was given a large number, and I looked at a variety of internal documents from that, from that that I selected myself.
Q. But all of the internal documents

that you were given came from the Plaintiff's Attorneys?
A. Yes. I would no other source of getting internal Bard documents.
Q. Now, did the Plaintiff's Attorneys provide you with the medical literature that you reviewed?
A. They provided me with some of the medical literature that I reviewed, and then I did multiple searches on my own and identified additional medical literature. I also looked through the references of most articles and identified further medical literature from those articles, from the references.
Q. Prior to your retention as a consultant in the filter litigation, had you ever conducted an extensive research or review of the medical literature related to IVC filters?
A. Well, as I said before, I do lots of meta analyses and systematic reviews, so the methodology that I used here is what I used in many of my previous studies, but I had never done this previously with inferior vena cava filters.
Q. Prior to your retention as a consultant in this case, had you ever read the

Kalva article?
A. I don't believe so.
Q. What about the Nicholson article?
A. Nicholson I recall. I am pretty sure I did see.
Q. What about the Binkert?
A. I am pretty sure I did not see that previously.
Q. What about the Asch?
A. Also the Asch article probably I did not see. Much of the literature in this area appears in the interventional radiology literature, and typically I am looking at the cardiology literature, internal medicine literature, New England Journal or JAMA. So most of these articles are not appearing in those types of journals.
Q. Just so it's clear for the record, if I understand what you are saying, most of the articles that you have reviewed regarding filters for this litigation don't generally appear in the periodicals that you routinely review as part of your professional work?
A. I think that's mostly correct. I mean, I do look at periodicals in other areas of

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medicine besides cardiology and internal medicine, but I don't routinely review articles in the interventional radiology literature unless I have a particular issue that I am going there for.

Q. We were provided a list of materials you had relied upon yesterday. Did that include all of the articles that you have reviewed for this case?

A. Yes, I believe so.

Q. Did you review the medical literature concerning complication rates of other manufacturers' filters?

A. I read some articles that involved filters made by other companies. That was not my focus but that was -- as an example, in the Grassi article many of the references were from filters that were not Bard filters, and I looked at some of those references as well.

Q. Is it fair to say that you did not review -- comprehensively review the medical literature to determine how the complication rates with Bard filters compared to the complication rates with competitive filters?

A. I would say I did review some

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articles that did those comparisons, but that was not my focus and I would not say I did a comprehensive review of that comparison.

Q. Well, it's my understanding that it's your opinion that the complication rate with the Recovery filter and the G2 filters was higher than the complication rate regarding the Simon Nitinol filter; correct?

A. Yes, that's one of my opinions.

Q. Have you done an assessment to see whether the fracture rate of the Recovery filter and G2 filter are higher than the Select filter?

A. I am sorry. Can you repeat that question, please?

Q. Have you done any assessment, as a part of your work, as to whether the fracture rate of the Bard filters is higher than that of the Select filter?

A. First of all, I haven't done any analyses of that sort. I have seen some articles looking at that, and one particular document I saw, which was a spreadsheet of complication rates of Select, and I believe it was a G2 comparison, but there was only one comparison. So I have seen some data related to that, but I

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can't say that I comprehensively reviewed that literature.

Q. And that would be true with regard to any of the complication modes, wouldn't it? Migration, tilt, penetration. You haven't done the comprehensive review of the literature to compare Bard filters with other manufacturers' filters?

A. Yes, I would -- you know, I would repeat what I just said was I have seen some of that literature, but I did not do a comprehensive review of Bard filters versus other company filters.

Q. Is it your opinion that the medical literature clearly establishes high complication rates for the Recovery and G2 filters?

A. I think that the totality of the evidence from the medical literature indicates that there is higher complication rates with Recovery and G2 versus the Simon Nitinol filter. There is clearly many studies out there documenting higher complication rates. The exact rates vary from study to study, but really the totality of the evidence from the medical literature demonstrates that there is a higher

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complication rate.

Q. So would you agree that anyone that looked at the medical literature could determine that the Recovery filter and the G2 had higher complication rates.

MR. ROTMAN: Objection.

MR. BUSMAN: Objection.

QUESTION WAS READ BACK.

MR. ROTMAN: Same objection.

THE WITNESS: I am sorry. Could you repeat it one more time, please?

QUESTION WAS READ BACK.

THE WITNESS: I don't think you could say anyone could look at that literature, because a lay person, I don't think, is capable of reviewing the medical literature. I mean, they just don't know the terminology. They don't study methodology. They really wouldn't be able to sort that out, but I would say that any clinician, excluding like psychiatrists, for example, would be able to read the medical literature and identify that there are higher complication rates with Recovery and G2 versus the SNF.

BY MR. NORTH:

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Q. You said there were multiple early safety signals with regard to these filters; correct?

A. I believe I said that, yes.

Q. And as one basis for that opinion you cited the MAUDE database. Is that correct?

A. Yes, that's correct.

Q. You did not conduct any independent review of the MAUDE database as part of your work in this litigation, did you?

A. I did not conduct any analyses of the MAUDE database myself. I did see what the -- [redacted] **In addition I, you know, spent a lot of time looking at the analyses done by Dr. Betensky, which is also MAUDE data, which I think very clearly demonstrates there is higher complication rates with Recovery and G2 versus the SNF. I did not do those analyses myself, but I did go through the spreadsheet and understand, I think, very well how the calculations were performed, and it was done according to the kind of standards that I would do if I were to do that**

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type of analysis.

Q. And prior to this litigation, your involvement in this litigation, had you ever had occasion to review the MAUDE database?

A. What do you mean by "review the MAUDE database"?

Q. Conduct some sort of study, some sort of analysis of a complication frequency rate or anything of that nature?

MR. ROTMAN: Objection.

THE WITNESS: I am sorry. Could you repeat the question, please?

BY MR. NORTH:

Q. I will rephrase it. Prior to your involvement in this litigation, had you ever had occasion to review the MAUDE database with regard to analyzing complication rates or frequencies with regard to devices?

A. So prior to this case I have not done any analyses involving the MAUDE database. I was aware of the MAUDE database. I am aware of studies that have used the MAUDE database, but within my own research I have not used the MAUDE database for studies.

Q. Have you ever sat down at a computer and accessed the MAUDE database?

A. I have accessed the MAUDE database.

Q. How many times?

A. Probably once.

Q. Was that as part of your work in this case?

A. Yes. I wanted to go back and see what it looked like.

Q. Did you read any of the FDA's discussions of the limitations of the MAUDE database?

MR. ROTMAN: Objection.

THE WITNESS: I believe that on the -- I don't recall where this document was, but I believe it was from the website itself that I read about potential limitations of the MAUDE database. It's possible it wasn't at that website, but I certainly have seen one or two documents describing the potential limitations of using the MAUDE database.

BY MR. NORTH:

Q. And what were those limitations, if you recall?

A. Some of the -- well, I can't give you an exhaustive list, but some of the

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limitations would be that there is known under-reporting with the MAUDE database, such that it is -- because it's a voluntary reporting system, it's suggested that many, many complications occurred that never get reported to the MAUDE database. So there is under-reporting. The second issue I believe that was mentioned is that -- that reporting rates can vary depending on if a device is newly released or if there was some media events, for example, that would make clinicians more aware if there is an issue and they would be more likely to report to the MAUDE database. Another limitation is that the -- in and of itself the MAUDE database can't really be used to calculate rates of complications because it's purely a numerator and it requires a denominator to generate rates. So those are some of the limitations that I recall offhand.

Q. As far as medical literature, you mentioned the Kalva, Nicholson, Asch and Binkert studies. As you sit here right now, can you recall the names of any the other studies?

A. I don't recall offhand.

Q. You also told me earlier that one of your opinions was that --

A. Can I just add to that? Although I don't recall offhand, I mean, there are a large number of studies that support that opinion, and I have gone over all of those papers, so I would have to get back to you with a comprehensive list of those studies.

Q. But as far as actual names, you don't recall any names?

A. No, but if you were, for example, to give me a name, I would probably recall whether I had reviewed that or not.

Q. Are you familiar with the Preserve study that is underway?

A. I am aware that it is a study that is ongoing, comparing different types of vena cava filters from different companies.

Q. You testified earlier that, in your opinion, it was Bard's responsibility upon having the data to conduct safety and efficacy studies regarding these filters; correct?

A. I believe that's correct.

Q. Let's talk about the source of this responsibility. Are there any FDA regulations that you can cite that would require Bard to conduct studies based upon the data that was

given?

MR. JOHNSON: Form.

THE WITNESS: Can you repeat that question, please?

QUESTION WAS READ BACK.

THE WITNESS: So I would say I am not an FDA expert, so I can't cite FDA regulations, but I am a clinician and a clinical epidemiologist. If I became aware of increased complication rates with a device that I was implanting in my patients or that my patients had I would really want the company to let me know and do the studies to show me that in fact it is safe and this is not real, or to identify that this is a problem and we need to stop using this device or remove it. So I think that although I can't cite FDA regulations, it's common sense that as a clinician or a patient you would want to know that information. You know, it's the company's product. They have to stand behind it and provide the data to show that it's not causing complications.

BY MR. NORTH:

Q. My question was to do with responsibility from the standpoint of the

company. I understand what you are saying about the clinician and patient. I am focused right now on the responsibility of the company, which you said. If you cannot cite an FDA or regulatory responsibility or requirement that these clinical studies be conducted under the circumstances, is the source of that responsibility, in your view, ethical?

MR. ROTMAN: Form.

THE WITNESS: I am not sure I understand the question.

BY MR. NORTH:

Q. You say they had a responsibility. That's the word you used. "Responsibility" generally means that there is -- something creates a responsibility. It can be a legal requirement, a regulation or it can be just a matter of good ethics. What is the source of this responsibility that you characterize here?

MR. JOHNSON: Form objection.

MR. ROTMAN: He testified.

MR. NORTH: He is testifying, not you.

MR. ROTMAN: That's right. So

objection, asked and answered.

THE WITNESS: Can you repeat it one more time, please?

BY MR. NORTH:

Q. From the standpoint of the company, you say they had a responsibility to conduct clinical studies, given the data that they had. You cannot cite a regulatory requirement or responsibility that they conduct those studies, so I am trying to identify what's the source of that responsibility. Is it because good ethics would require it? Is it because of a regulation we haven't talked about? What is the source of that responsibility?

MR. JOHNSON: Form.

THE WITNESS: Maybe I could give an example which would be if, you know, you are driving a Honda Civic and there is a problem with the air bag, and this problem with this air bag is much more common with a Honda Civic than another brands. And the company knows about it. Maybe they have got to find out if this is a statistical aberration or is this a real problem and we have to fix it? Do we need to recall the car? The people that are driving it need to

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know. Even the people that are selling it need to know. So it's the same thing with this situation with Bard and with Recovery and G2. If there is an indication from you know, the MAUDE database or clinicians are saying: We are seeing complications that we didn't see before. We are seeing them at a higher rate than we have seen before. The clinicians did what they could do. For example, they would look back at their database at their hospital and see all the patients that had it implanted, an IVC filter, and look at the complication rate. But the clinicians are not in a position to do a multi-centre study looking at this. They are not in a position to set up a randomized control trial comparing Recovery versus SNF. It's the responsibility of the company to do that if there is a concern that there is a safety issue here. Is it an ethical issue? I mean, is the basis of this ethical? I don't know. As I said before, I am not ethics expert, but it seems like common sense for the average person that the company that is producing this, if there is an issue it's their responsibility to put that issue to rest one way or the other. Could I add to that? I

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think that opinion was expressed, I think, by Murray Asch as well when he did his, you know, his pilot study and had complications. And he understood that the company was going to do a large study after this to look at safety and efficacy, and it was never done and he felt misled in that sense. He recognized that the study that he did was a retrievability study which was not powered to look at complication rates, and that that needed to be done.

BY MR. NORTH:

Q. You mentioned in discussing the Grassi article that you believe the comparisons made by Bard were apples and oranges comparisons. Explain what you meant by that.

[redacted]

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[redacted]

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[redacted]

Q. Prior to your involvement in this litigation, were you aware of the claim by many people that the MAUDE database is affected by under-reporting?

A. You say "many people". I don't know what that means exactly. I knew before my involvement in this case about the MAUDE database. I knew that under-reporting was, you know, a limitation or potential limitation of the database.

Q. You don't know about Bard's particular policies and procedures of reporting adverse events to the MAUDE database, do you?

MR. ROTMAN: Objection.

THE WITNESS: I am sorry. Can you repeat that question, please?

BY MR. NORTH:

Q. You do -- you have not studied Bard's own policies and procedures for reporting adverse events to the MAUDE database, have you?

A. I can't say that I have gone through every internal Bard document about their policies about reporting to the MAUDE database.

Q. And you can't -- you haven't made any assessment as to whether Bard reports more or reports less events than the competitor manufacturers, can you?

A. I am not sure what you mean by that. Could you repeat that?

Q. Have you made any study as to how Bard's standards for reporting events to the MAUDE database compare to the standards of other manufacturers?

A. I have not made a study of that and, as I say, I haven't looked exhaustively at the Bard documents about reporting, and I have no access to internal documents about other companies about their standards about reporting to the MAUDE database. It's my understanding that the companies are supposed to report all their complications to the MAUDE database, but as to whether that actually happens and whether

there is any coding problems, I can't speak to that.

Q. With regard to the safety signals that you believe the data demonstrated, were those signals statistically significant?

MR. ROTMAN: Objection.

THE WITNESS: You know, the safety signals come from a couple of different sources. As I mentioned, they come from the MAUDE database and also the Betensky analyses which is derived from the MAUDE database. They come from the medical literature and they come from the Bard internal data about migration resistance. So I [redacted] that it should be looked into. The Betensky analyses which replicate the MAUDE database analyses actually show highly statistically significant differences between the Recovery and SNF and between the G2 and SNF and, in fact, I believe that Dr. Betensky found some reporting errors between Bard and the MAUDE database, I think some transcription errors which actually

even magnified the size of the complication rates. They were clearly statistically significant in her analyses. The second group of data, second source of data here of increased complications comes from the medical literature, so the medical literature, there has never been a randomized controlled trial, to my knowledge, of Recovery versus SNF or G2 versus SNF. So they have not reported statistically significant or not statistically significant data. Most of the studies reported are registry data, so they follow a group of patients with the Recovery filters and then report complication rates. So they don't typically report statistical significance. That could be done if a meta analysis had been done. I think the company should have and could have easily done a meta analysis of all the reports from the medical literature and would have been able to provide some statistical information, but again the totality of the evidence from the medical literature, it's overwhelming that there is complication rates with these retrievable filters. And the last bit is the migration resistance testing was done internally in Bard

and, as I understand, that was also statistically significant, I believe, although I am not as -- I didn't have complete access to that internal testing data, or perhaps it was in the documents I had but I didn't see it all.

BY MR. NORTH:

Q. You have mentioned a number of sort of sources of information: Dr. Betensky's analysis, the consultant's analysis. Did you make any independent assessment as to whether the complication data showed a statistically significant safety signal?

A. Can you repeat that again?

Q. Okay. You tell us the data showed a safety signal. Did you independently yourself calculate whether that signal was statistically significant?

A. So you know, I do a lot of this research, this type of research in my regular practice where I do systematic reviews and meta analyses. So I am quite experienced in looking at the totality of evidence from multiple sources to do that determination. I did not do any analyses myself. I think that, you know, I went over in detail the Betensky analyses and I am

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very comfortable with those analyses. The analyses by the Bard internal consultant, I didn't have access to those analyses, so I couldn't replicate that. But I am not sure it's such an issue. If a company hires a consultant to look at their data and the consultant says: There is a problem, you better look at it, I think the company needs to treat that seriously. The -- in terms of the medical literature, I am capable of pooling the data from all these different reports. I haven't done it, but it could be done. I think it could have been done by Bard and should have been done. It still is possible it could be done.

Q. In all the medical literature that you have reviewed, have you seen any case report or instance where a Bard filter tilted an entire 90 degrees?

MR. JOHNSON: Form.

THE WITNESS: I have seen many, many, many reports of tilted filters and I think that the definition of -- what's considered a tilted filter is more than 15 degrees. So there has been large numbers of patients with Bard filters that have tilted more than 15 degrees.

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As to whether they have been more than 90 degrees, I am not sure I could tell you that it was exactly 90 degrees. There certainly have been cases of complete embolization of Bard filters.

BY MR. NORTH:

Q. I am not asking about embolization. I am asking about where the filter simply tilts. Can you recall seeing any specific report of a Bard filter tilting 90 degrees?

MR. JOHNSON: Form.

THE WITNESS: I don't recall seeing that exactly, but again, I would say that I didn't go exhaustively through the case reports. I focused on the case series, and the cohort studies and the retrospective cohort studies. So individual cases, it's quite possible that there are cases if Bard filters tilting 90 degrees, but I can't point you to one.

BY MR. NORTH:

Q. You have talked about overall complication rates, that you believe the complication rates for the Recovery and G2 exceed the complication rate of the Simon Nitinol filter. Let's look at one specific complication.

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For tilt and tilt alone, do you know how the complication rate of the Recovery filter compares to the Simon Nitinol filter?

A. I would have to refer back to the Betensky analyses. So if you showed me the spreadsheet I could walk you through the numbers.

Q. As you sit here now, without consulting Dr. Betensky's spreadsheet, do you know whether the data showed that the Recovery filter tilted more often than the Simon Nitinol or not?

A. There were multiple studies in the medical literature, case series registries, cohort studies, retrospective cohort studies looking at, for example, all patients in an institution that had a retrievable filter put in and then they report tilt rates. The tilt rates are -- they are high. They are different in different studies. There has been, at least since 2000, there has been very few, if any, reports of tilt with the Simon Nitinol filter in literature that I am aware of. To do a -- so that in itself is telling. We are seeing lots and lots of reports with tilts and other complications with retrievable filters over a

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16-year period, and very few, if any, complications with a Simon Nitinol filter over that period in the medical literature; okay. I mean, really, what you would need -- what you would really like to see as a clinician is a head-to-head trial of patients randomized to a Simon Nitinol filter versus a retrievable filter, and follow them forward with systematic imaging to see.

Q. Move to strike the answer as not responsive to the question. Dr. Eisenberg, you kept answering the question in terms of studies of retrievable filters. My question didn't have to do with the generic term "retrievable filters". It had to do with the Recovery filter.

A. Yes.

Q. Do you know whether the data shows that the Recovery filter has a higher tilt rate than the Simon Nitinol filter?

A. Yes, I think the data is quite clear that the tilt rate is higher with the Recovery than it is with the Simon Nitinol. The Betensky analyses showed very clearly. It was also shown in the analyses done by the consultant with the MAUDE database for Bard. And in the medical

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literature there has been very studies, as I say, of registries, cohort studies of the Recovery which show tilt. Over that same time period we have virtually no reports of tilt with the Simon Nitinol filter, so I think the totality of the evidence is quite convincing, very convincing that there is more tilt with Recovery than with the Simon Nitinol filter.

Q. Without the support of Dr. Betensky's data analyses would you be able to express an opinion as to whether the complication rates of the Bard filters, retrievable filters exceed that of the Simon Nitinol filter?

MR. JOHNSON: Objection. Form objection.

BY MR. NORTH:

Q. In a statistically significant fashion?

A. So in the absence of the Betensky analyses, then I would have to do those analyses myself and I -- I am very comfortable that my analyses would replicate what Dr. Betensky has done, and because she found highly statistically significant differences, I am sure I would find the same thing. But aside from that, we have the

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Bard consultant who did those analyses and found statistically significant differences. So we have that, and we have Betensky and we have many, many reports in the literature of complications associated with Recovery and virtually no reports of complications with SNF.

[redacted]

Q. If that's true, then the only source of your opinion that the complication rate of the

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G2 is higher than that of the Simon Nitinol in a statistically significant fashion is Dr. Betensky's analyses, which we discussed.

MR. ROTMAN: Objection.

THE WITNESS: Well, in addition to that we have -- we have several studies that -- that compared the G2 to Recovery. So these were not randomized controlled trials, but they were studies where they looked at a group of patients who got Recovery or a group of patients who got G2 and compared their complication rates. And the complications we are seeing with the G2 were similar in incidence to the Recovery.

BY MR. NORTH:

Q. So it's your testimony that the complication rates for the G2 were equivalent to the complication rates -- equivalent to the complication rates for the Recovery filter?

A. In some studies. In addition, if I am not mistaken, in the Binkert study they also demonstrated that the migration rate or at least the caudal migration rate was much, much higher than had been reported to Recovery. So although we don't have direct statistical evidence, we have evidence that G2 had a high complication

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rate. Recovery had a high complication rate. Recovery was statistically different than SNF but, in any case, we still have the Betensky analyses which I think are overwhelmingly convincing that complications with G2 are much greater than SNF.

Q. That's not my question. I am talking about G2 versus Recovery filter.

A. Yes.

Q. Did the Betensky analysis show that the G2 rate was equivalent to the Recovery rate as far as complications go?

MR. JOHNSON: Form.

THE WITNESS: I don't believe that they did a direct analysis, a direct comparison of G2 versus Recovery, although that could be done with the data that's available.

BY MR. NORTH:

Q. We were talking a few minutes ago about the tilt rate comparing Recovery and Simon Nitinol. Is it your belief that the tilt rate with the G2 is higher than that of the Simon Nitinol?

A. Yes, it is.

MR. JOHNSON: Are we going to take a

lunch break?
MR. NORTH: Let's take a pretty quick one.
BY THE VIDEOGRAPHER: Going off the record at 12:53 p.m.
BY THE VIDEOGRAPHER: This begins disk number three in the deposition of Dr. Eisenberg. We are back on the record at 1:47 p.m.
BY MR. NORTH:
Q. Good afternoon, Doctor. Could you tell me when, in your opinion, the evidence first showed a safety signal that the G2 had a higher tilt rate than the Simon Nitinol?
A. I would have refer to the Betensky analyses to tell you when that happened. I would really need to have the spreadsheet in front of me with the analyses.
Q. Did you make any independent analyses of when that safety signal first became apparent?
A. Well, I mean, I did my own analyses of the data that was presented in the spreadsheet, but I didn't do any actual calculations myself.

Q. And would that be true as to any complication mode that you would have to refer to Dr. Betensky's calculations that determine when a safety signal first became apparent with regard to G2 vis-à-vis the Simon Nitinol filter?
A. There are several sources of evidence here. So the Betensky analysis nicely lays out, according to different dates, how much data had accumulated and, you know, what the reporting relative risk ratios were and when they were statistically significant, and in a very quantitative way. But in the medical literature, you know, you see reports of this coming out. So I would have to go back, and again I don't have it in front of me. But you could see reports coming out of registries, cohort studies of the G2 reporting rates of tilt and fracture and migration, et cetera. So I would have to go back and actually pinpoint when those were actually published and when the data was from.
Q. In other words, you would have to go back and consult the medical literature and/or Dr. Betensky's analysis to pinpoint a date when the safety signals first became apparent. You can't tell us that off the top of your head, sitting here right now?
A. That's right. I would need the data right in front of me.
Q. Doctor, have you attempted to construct a clinical study that you believe should have been conducted here?
A. I haven't constructed a clinical study but I have given some serious thought to what types of studies should have been done and what they would look like, if that's what you are asking.
Q. Yes. Well, tell me what you have come up with in that regard.
A. Well, I think that most people would agree that a randomized controlled trial is the gold standard for safety and efficacy in the medical world. So if you want to say that the Recovery is substantially equivalent to the predicate device, which is the SNF, you would ideally do a randomized controlled trial, randomizing patients to SNF versus Recovery and then follow them forward with systematic imaging and clinical follow-up long-term to see what the outcomes are. And if you have an adequate sample size and therefore, the power, you can identify whether they are substantially equivalent both for efficacy and for safety.

Q. Would it be ethical to conduct a study like that, given the fact that you might end up putting permanent filters in some people that should have retrievable filters and vice-versa?
MR. JOHNSON: Form.
THE WITNESS: I think that -- I think that when the Recovery filter was first available for commercial use and the G2 as well, they were marketed as the permanent filters, so they -- it would certainly be -- excuse me -- clinically ethical to randomize patients who need a permanent filter to either an SNF or a Recovery, because they were marketed and were said to be okay to leave in permanently. So I think that would be reasonable to do. If you had a patient who you said this patient for sure needs a retrievable filter, they would probably not be a candidate for that study.
BY MR. NORTH:
Q. How long do you think, in general terms, it would take to complete such a study?
MR. ROTMAN: Objection.

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THE WITNESS: I think -- you know, I did analyses looking at sample sizes, and I think in order to do an adequately powered clinical trial you would need hundreds and perhaps thousands of patients for a trial like that. But I think that a multi-centre trial can randomise patients very quickly. These kinds of filters were being widely used and I think there would be many centres that would be interested in participating in such a trial. So I think that the patients could be randomized fairly quickly. Most of the studies that I saw only had six-month follow-up for their filters. I would like to see longer follow-up than that and, at a minimum, you would have six-month follow-up and then you could have 12 months with systematic imaging. So I think it would take several years to do.

BY MR. NORTH:

Q. Talking about sample size, the three sets of calculations that we marked as Exhibits that you did concerning confidence intervals and sample sizes, tell me a little bit more about why you did those for this case.

MR. ROTMAN: Objection.

THE WITNESS: Well, I think it was

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clear that there was a safety signal early on, and the company was aware of this and it should have been followed up with clinical studies, ideally a clinical trial. We are just talking about clinical trials. I think there is other studies that could be done as well, ideally a clinical trial, but if not a clinical trial, then a meta analysis. A large registry could also be done, which we could talk about if you like. But in considering a clinical trial, when I was doing these calculations I was thinking along the lines of if you were to do a clinical trial, how large a clinical trial would you need to do in order to really address this issue to say, yes, there is a difference in complication rates or no, I can safely say there is no difference in complication rates. So the sample size estimates that I calculated were based on -- I looked at different rates of complications and different sample sizes to see what kind of confidence interval you would have or what the sample size would be in order to have adequate power to look at differences in postulated complication rates.

BY MR. NORTH:

Q. Am I correct that those are sort of

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general calculations and there is nothing within the calculations that relies on data specifically tied to filters?

A. That's not quite true. One of the calculations which was -- it's been labelled as Exhibit 4 is sample size calculations if one were designing a study to see if Recovery had a significantly higher complication rate than the rates quoted in the Grassi article. So for example, if -- in the Grassi article they are recording a death rate of less than one percent. If you wanted to identify a death rate of ten percent or more, which is huge, the minimum you would require would be 100 patients per arm, so 200 patients in a trial. But that's a more than ten-fold difference in death rates. And for death you would obviously want much more confidence that there was no difference between the two, so you would need a much larger study than that. So I used the numbers in the Grassi article just as, you know, a comparison for one arm.

Q. Do you know whether the FDA has the same complication data that you have reviewed?

MR. JOHNSON: Form.

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THE WITNESS: I am not sure what you mean.

BY MR. NORTH:

Q. Do you know whether the United States Food and Drug Administration has reviewed the same complication data that you have reviewed?

A. As far as I am aware, they have not seen the Betensky analyses and I am -- you know, I am not -- I don't know what Bard reported to the FDA, so I don't know what the FDA is aware of. They have issued some warnings. They are clearly aware that there is issues with retrievable filters. And also there is many -- as I mentioned, there is many reports in the literature, but I don't know if the FDA actually looks at them on an ongoing quantitative manner or whether, for example, the company is supposed to bring it to their attention. I don't know that process.

Q. Are you able to pinpoint, as you sit here today, able to pinpoint for me the point in time when you think it became obvious in the medical literature that the Recovery filter and G2 filter had excessive complication rates?

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MR. JOHNSON: Form.
THE WITNESS: Again, you know, I would have to have the articles in front of me to see their publication dates and also when the data was collected. But the HHE, again there is one particular HHE where the Bard internal consultant was reporting higher rates. I believe it was from 2004. So I believe that the Recovery was released in 2003 or very, very late in 2002 and that by 2004 there were reports of complications with the Recovery. The G2, I would have to go back and look.
BY MR. NORTH:
Q. Even in the Recovery, that wasn't in the medical literature. I am talking about just medical literature. Do you know when it became obvious in the medical literature that there were excessive complications with the Recovery filter?
MR. ROTMAN: Form objection.
THE WITNESS: I am going to have to look back. I think the Asch article which was a retrievability study, and in the first 32 patients there was a case of significant migration and in the 33rd patient, which was not reported in that article, there was fracture

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which is -- you know, so this is a signal for a clinician. If you see something in a relatively small number of patients, that's alarming. One would say: We need to look at this in a bigger sample size. But again, I don't recall exactly what year that was published. I think it was pretty early on, because that study was done even before the Recovery was released, as I recall.
BY MR. NORTH:
Q. Have you shared any of your concerns about Bard filters with the radiologists at your hospital?
A. No, I have not.
Q. Have you shared any of your concerns about Bard filters with anybody at your hospital?
A. I have not, and part of that is my understanding is this is all privileged information and I really shouldn't be talking to anybody about this stuff, if I am not mistaken. Isn't that correct?
Q. I get to ask the questions, sir. So the answer is you have not?
A. No, I have not.
Q. Okay. You talked about these advisory boards for pharmaceutical companies that

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you had been a member of. Have you ever been directly employed by a pharmaceutical company or a medical device company as opposed to consultant work?
A. No, I have never been an employee of a pharmaceutical company.
Q. Am I correct that Dr. Betensky calculated a relative risk for the complications of the G2 and the Recovery filter?
A. She calculated what she called a reported relative risk -- reported relative risk ratios. So what she did was she calculated the relative risk for the Recovery and the relative risk for the Simon Nitinol filter, and then she divided the Recovery number by the SNF number to come up with her reported -- reporting relative risk ratio.
Q. Are you familiar with the concept of a reported relative risk ratio?
A. I am certainly -- I know about relative risk and relative risk ratios. The reported relative risk ratio, I think, is just referring to the fact that there may be under-reporting in the MAUDE database. So these are reported cases rather than prospectively

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documented in a clinical study.
Q. Are you aware of any statistical -- or literature concerning statistics or literature concerning epidemiology that defines the term "reported relative risk ratio"?
A. I -- you know, I have pretty extensive training in epidemiology but this, I think, is a concept that's probably in a very narrow area of epidemiology dealing with databases like the MAUDE database. So it's not a typical thing that I calculate. It's not a typical thing that I am using. I use relative risk ratios, but it's -- what I believe is the reporting or reported part is only referring to the fact that these are reported numbers in the MAUDE database.
Q. Well, prior to your involvement in this case, in discussions with Dr. Betensky, were you aware of a data point called the reported relative risk ratio?
A. I don't believe I was.
Q. Would you rely -- not rely. Would you defer to Dr. Betensky as to the limitations of the data and analysis she used?
A. Sorry? Could you repeat that?

Q. Would you defer to Dr. Betensky as to the limitations on the data that she used for her analysis?

A. I am relying on her data. I think her data is robust. I respect her credentials as a biostatistician. I think her analyses are correct. Defer to her? I view it more as I am on the epidemiology side and she is on the biostatistical side. So I have more of a clinical sense of what these numbers mean and she has more of the numerical sense. So I think it's more of a collegial effort.

Q. Well, would you defer to Dr. Betensky as to any limitations on the data she used for her analysis from a statistical point of view.?

A. I am not sure what you mean by "defer". You mean if she suggested there was a potential limitation, would I agree that that might be a potential limitation?

Q. Well, if she suggested there were potential limitations would you take issue with her?

A. No. I agree there is potential limitations with this type of analysis.

Q. Would you agree that, to your knowledge, Bard did not violate a regulatory duty by not conducting the sort of clinical study you have proposed?

MR. JOHNSON: Form objection.

THE WITNESS: Can you repeat that, please?

BY MR. NORTH:

Q. Would you agree that. To your knowledge, Bard did not violate a regulatory duty in not performing the sort of clinical study you have advocated?

MR. JOHNSON: Objection.

MR. ROTMAN: Objection.

THE WITNESS: Can you repeat it one more time?

QUESTION WAS READ BACK.

THE WITNESS: So I really can't speak to that because, you know, as we discussed earlier, I am not an FDA expert, so I don't know what the regulatory requirements are. But you know, as a clinician I would say, you know, my expectation would be that if there was a signal that it would be followed up by the company that made the product. But regulatory-wise I can't

speak to that.

BY MR. NORTH:

Q. Do you believe that Bard violated an ethical duty by not conducting the sort of study you have advocated?

MR. JOHNSON: Form.

THE WITNESS: Sorry. Could you repeat that one again also?

BY MR. NORTH:

Q. Do you believe that Bard violated an ethical duty by not performing the sort of clinical study you have advocated?

A. Again, I don't put myself out as an expert on ethics, so I can't really speak to that. I think that if you ask most clinicians and most patients, they would say yes, Bard had an ethical duty to follow up the signal with an adequately powered and designed study. But as to whether an ethicist would say that, I don't know.

Q. Are there any objective criteria that define when a safety signal such as you have described here arises?

MR. ROTMAN: Objection.

THE WITNESS: It's possible in the, for example, pharmacovigilance literature there

is a -- that's an issue, and you alluded earlier to an FDA definition for a signal. But for an individual clinician even one case report or one case that's not reported of a new complication that you have not seen before to me is a safety signal. So if you see something that you have never seen before, you say what's going on here? Is this happening in other places? We need to look at this. That's the whole reason we have case reports, and the case reports go back decades and decades, because that was the early sentinel system for safety issues. So if you reported your case reports and somebody else in Alaska reported the same safety issue and somebody else in Texas reported it, all of a sudden you would say: There is an issue here. That's how AIDS was identified, just from a handful of cases. So for me, as a clinician, I would say one case is enough if it's a complication that's not been seen before. But it's possible that there are objective definitions with different organizations, but I don't know them offhand.

BY MR. NORTH:

Q. So do I understand, from your

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standpoint a single case report can create -- I am sorry, a case report of a complication can create a safety signal?

A. For me as a clinician, I would say yes, if you see a new retrievable filter has been put out and all of a sudden you see one has migrated to the right ventricle and is causing ventricular tachycardia and death and you have never seen that before, you would say: This is a big safety issue. We have got to stop putting these in and look and see if anybody else has had these kind of complications. In terms of clinical epidemiology, you start with a case or a series of small cases and then you put together a study to see if that in fact is a real safety issue or not. But depending on the severity of the presentation; yes, one case can be a safety signal.

Q. Do you believe that that is a standard belief among all clinicians that a single case report can create a safety signal?

MR. JOHNSON: Form objection.

THE WITNESS: Yes, I do believe that, and again I draw us back to the AIDS situation. The first patients showed up. There

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were gay men with Kaposi's Sarcoma, which is a very, very rare condition which you never see except in immunocompromised people. And alert physicians reported it, and then there were a couple more reports, and then they looked into it and there was an epidemic. That was the tip of the iceberg. So I would say that most clinicians would say: Yes, a single case report can be a signal, depending on its severity. And if it's something you have never seen or heard of before it can be a safety signal and should be reported.

BY MR. NORTH:

Q. Have you read any depositions in the filter litigation by a Dr. David Feigal?

A. Yes, I did.

Q. Do you know Dr. Feigal?

A. No, I don't.

Q. Do you have any specific criticisms of his opinions that you read?

MR. JOHNSON: Form objection.

THE WITNESS: I read the deposition a while ago, so I would have to re-read it before I could speak to that question.

BY MR. NORTH:

Q. Have you read any depositions by Dr.

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Clement Grassi?

A. Yes.

Q. Same question. Do you have any specific criticisms of his opinions?

MR. ROTMAN: Form objection.

THE WITNESS: Well, again this is -- I read it a while ago, so I would have to, you know, re-read it in order to get back to you, but there are two things that I recall from that deposition. One is he said in his deposition that the article I referred to as the Grassi article was not a guidelines article but was rather a quality assurance article, and that the numbers given in that article should not be taken as thresholds for safety but rather thresholds that should be used by hospitals to initiate a root-cause analysis if they see that they are approaching these numbers. So that's what he said in his deposition and I agree with that. The other -- one other thing he said in his deposition, which I don't agree with, is that if you have patients with retrievable filters that are having complications -- interventional radiologists like Dr. Asch feel those patients should be followed in a systematic manner with

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regular imaging and Dr. Grassi said -- if I recall correctly, that -- that the follow-up should be personalized to the individual patient rather than doing routine systematic monitoring of these patients, and I don't agree with that. I think that patients with a retrievable filter really need regular systematic follow-up with imaging in order to identify problems with the filters.

BY MR. NORTH:

Q. Do you know Dr. Grassi?

A. No, I do not.

Q. Have you read any depositions of Robert Carr?

A. Yes, I have.

Q. Do you have any specific criticism of Mr. Carr or his testimony?

A. Again, I read -- I guess there is more than one deposition by Mr. Carr, and I read them a while ago, so I would really have to re-read them in order to speak to any specific point.

Q. Have you read a deposition or depositions of Andre Chanduszko?

A. I read that deposition and I read

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that a long, long time ago, and so I don't have much recollection of that. So again, I would have to re-read that in order to speak to that.

MR. NORTH: That's all the questions I have.

MR. ROTMAN: Let's take a break. We may be done. We may have a few questions.

BY THE VIDEOGRAPHER: Going off the record at 2:19 p.m.

BY THE VIDEOGRAPHER: Going back on the record at 2:28 p.m.

CROSS-EXAMINATION

BY MR. ROTMAN:

Q. Dr. Eisenberg, good afternoon.

A. Good afternoon.

Q. Thank you for your testimony this morning. I do have a question for you, just to go back over one of the topics that came up before lunch. Do you remember you were asked some questions about your background and experience in reviewing internal documents of medical device companies?

MR. NORTH: Objection, leading.

BY MR. ROTMAN:

Q. Do you remember that series of

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questions?

A. Yes, I do.

Q. And do you recall at one point you provided an answer about whether reviewing -- whether reviewing an internal document required particular expertise?

MR. NORTH: Objection, leading.

THE WITNESS: Yes, I recall that.

BY MR. ROTMAN:

Q. What -- can you explain your answer on that issue?

MR. NORTH: Objection.

THE WITNESS: Yes. I am glad you asked, because I think I was not as clear as I could have been, which was, I think -- I think that when you read internal company documents for a device company there are certain things that a lay person can read and understand such as crisis management, alarmingly high rate. So there are things that do not require particular expertise to understand. But let's face it, this whole area is dealing with things that a lay person could not understand, that you need to be a medical expert of some sort in order to even know what an IVC filter is, to know what tilt, to know

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what perforation, embolization, fracture. All of those issues, you need to be an expert in order to read the documents. In order to know about relative risk and statistically significant differences you need to have some epidemiologic biostatistical background. To know about -- and I only went through a very small portion of the internal documents, but in order to, you know, to look at the totality of the internal documents and see how the company dealt with the FDA, for example, you would need somebody who was an expert, you know, with FDA industry relations, which I am not. So I think that while there are, you know, an isolated communication, some of them a lay person might be able to read and certainly would potentially be alarmed at. Other internal documents you clearly need different types of expertise. For example, you know, migration testing, you need somebody who knows about in vitro testing which, you know, I don't portray myself as an expert in that area. So I think you need different types of experts in order to read and interpret different parts of, you know, internal company documents.

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BY MR. ROTMAN:

Q. I have no other questions.

RE-DIRECT EXAMINATION

BY MR. NORTH:

Q. Doctor, you had lunch today with Mr. Rotman, Mr. Mankoff and Mr. Johnson; correct?

A. Correct.

Q. And did you all discuss your testimony concerning whether lay people can understand these company documents?

MR. ROTMAN: Objection. Work product.

MR. NORTH: Are you instructing him not to answer?

MR. ROTMAN: Yes. Also attorney/client privilege.

MR. NORTH: On what grounds? Do you represent him? Are you his Attorney?

MR. JOHNSON: It's work product. We will say it on that.

MR. ROTMAN: It's work product.

BY MR. NORTH:

Q. But you did have lunch with these three gentlemen, didn't you?

MR. ROTMAN: You already answered

that.

THE WITNESS: Yes, I did.

MR. NORTH: No further questions.

MR. JOHNSON: We will read.

BY THE VIDEOGRAPHER: This concludes the deposition of Dr. Mark Eisenberg. Going off the record at 2:33 p.m.

UPON ADJOURNING AT 2:33 P.M.

C E R T I F I C A T E

I, C.L. KLEIN, Official Court Reporter, duly sworn as such, DO HEREBY CERTIFY that the foregoing is a true and faithful transcription of the evidence herein, AND I HAVE SIGNED:

<%Signature%>

C.L. KLEIN, O.C.R.

August 22, 2016

Re: Austin v. C.R Bard, et al

Case No.: CACE-15-008373 DIV: 07

Please take notice that on the 17th day of August 2016 you gave your deposition in the above cause. At that time, you did not waive your signature. The above-addressed attorney has ordered a copy of this transcript and will make arrangements with you to read their copy. Please execute the Errata Sheet, which can be found at the back of the transcript, and have it returned to us for distribution to all parties.

If you do not read and sign the deposition within a reasonable amount of time, the original, which has already been forwarded to the ordering attorney, may be filed with the Clerk of the Court.

If you wish to waive your signature now, please sign your name in the blank at the bottom of this letter and return to the address listed below.

I do hereby waive my signature.

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MARK J. EISENBERG

ERRATA SHEET

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In Re: AUSTIN V. C.R BARD, ET AL

Case No.: CACE-15-008373 DIV: 07

MARK J. EISENBERG

August 17, 2016

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Under penalties of perjury, I declare that I have read the foregoing document and that the facts stated in it are true.

Date MARK J. EISENBERG

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